HFI-35
No pumping needed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M34/4N

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850

FEB 17 2000

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Rich Lunsford
President
Sulzer Spine-Tech
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2029

Re: BAK Interbody Fusion System, P950002

Dear Mr. Lunsford:

The Food and Drug Administration (FDA) has reviewed two "Dear Dr." letters sent to physicians by Dave R. Furey, a Sulzer Spine-Tech sales representative. These letters concerned the use of the BAK Interbody Fusion System and Mr. Furey's impressions of Sofamor Danek's Interfix cage. The letters were dated June 7, 1999, and September 14, 1999, respectively. The BAK Interbody Fusion System (BAK System) is manufactured by Sulzer Spine-Tech and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The BAK System has been approved through the Premarket Approval Process (PMA) pursuant to section 515(d)(1)(B)(ii) of the Act and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK devices are to be implanted via an open anterior or posterior approach. The BAK device is also indicated for laparoscopic implantation at the L4-5 and L5-S1 levels for the same clinical indications described above.

The agency believes that Mr. Furey's letters contain misleading statements with respect to the Interfix Threaded Fusion device (Interfix). Statements in Mr. Furey's letters imply that the Sulzer Spine-Tech BAK device is more effective than the Interfix device. The agency has not received any evidence from Sulzer Spine-Tech to support these claims, nor has the agency concluded that the Interfix device is not safe or effective for its intended use. Both the BAK and the Interfix devices were approved by the agency based on clinical data demonstrating that both devices are safe and effective. Representations that the agency objects to include the following:

1. Sulzer Spine-Tech's conclusion (based on results obtained from an early baboon study) that smaller holes made it easier for fibrous tissue to block or impede fusion implies that the larger holes of the BAK System result in a more successful clinical outcome. The agency has no evidence that the size of holes, in either the Interfix device or in the BAK device, impacts overall fusion results.

2. Mr. Furey's June 7, 1999 letter states that the use of endcaps in the Interfix device is required to ensure proper strength and implies that the BAK System is stronger because endcaps in the BAK System are optional. No data have been provided to the agency to show that endcaps in the Interfix device are needed to ensure proper strength. Additionally, there is no evidence to support the claim that "by countersinking implants and packing bone in front of the device you greatly enhance grow-through and bone-bridging fusion" or that the ability to gauge fusion is affected by the presence of endcaps.

3. Mr. Furey claims that the square thread design of the BAK System increases the press fit and reduces subsidence. No data have been provided to the agency to support this claim.

4. We object to claims that approval of the Interfix device is limited to non-smokers. Sofamor Danek's approval of the Interfix device did not have any restrictions or limitations regarding smoking.

5. Claims that the Interfix study was comprised of a small sample group of approximately 200 patients resulting in less experience for that device, and claims that the BAK System has been implanted in over 40,000 patients are misleading. The actual clinical trial for Interfix consisted of 181 patients (77 randomized; 104 non-randomized). In the BAK clinical trial, successful fusion rates at 24 months for all study subgroups was based on a total of 267 patients; study success rates at 24 months for all study subgroups was based on a total of 254 patients. Therefore, total patient populations used for the final analysis for both devices are comparable. Additionally, it is not unreasonable to expect the Interfix device to have been implanted in a much smaller number of patients since that device was recently approved (May, 1999), versus the BAK System which was approved in September, 1996, almost 4 years earlier.

6. We object to the representations made in Mr. Furey's letter which compares overall success rates and successful fusion rates for the BAK System to an intent-to-treat analysis for the Interfix device. This results in an unequal comparison i.e., the percentages reported from the Interfix device were based on an intent-to-treat analysis which included patients with secondary surgical failures, deaths, patients lost to follow up, and missing observations due to other causes. Inclusion of these

parameters in the intent-to-treat analysis makes the overall success rates and fusion success rates for the Interfix device appear to be much lower than they really are (or makes the BAK System appear to be falsely superior). Additionally, the success criteria for each device used different parameters. The Interfix effectiveness analysis included: assessment of fusion at the involved level, pain/disability status, neurological status, general health status, disc height status, and overall success. In contrast, the BAK System effectiveness analysis included fusion of the involved vertebrae, pain, function, and muscle strength. Therefore, a direct comparison between the two devices would be inappropriate.

Additionally, the agency has determined that before a manufacturer may make a direct comparison of their orthopedic device with that of another manufacturer, randomized, controlled, head-to-head clinical trials would be required.

Under the provisions of 21 CFR 801.6, a manufacturer making a false or misleading statement with respect to another device causes his own device to be misbranded. All of the above claims for the Sulzer Spine-Tech BAK System (identified in Mr. Furey's letters) cause your device to be misbranded under 21 CFR 801.6. The Sulzer Spine-Tech BAK System is also misbranded within the meaning of section 502(a) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with your BAK Interbody Fusion System. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Minneapolis District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Minneapolis District Office (HFR-MW300), 240 Hennepin Avenue, Minneapolis, Minnesota 55401-1912.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health